



01-17-06

PATENT

Attorney Docket No. UM-08550

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Joseph Holoshitz *et al.*

Serial No.: 10/786,774

Filed: 02/25/04

Entitled:

Methods And Compositions For The Treatment Of
Diseases Associated With Signal Transduction
Aberrations

Group No.: 1649

Examiner: Standley, S.

INFORMATION DISCLOSURE
STATEMENT TRANSMITTALCommissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.10

I hereby certify that this correspondence (along with any referred to as being attached or enclosed) is, on the date shown below, being deposited with the U.S. Postal Service in an envelope as "Express Mail Post Office to Addressee" Mailing Label Number **EV769933010US**, addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Dated: January 12, 2006By: Thomas W. Brown

Thomas W. Brown

Sir:

Enclosed please find an Information Disclosure Statement and Form PTO-1449, including copies of the references contained thereon, for filing in the U.S. Patent and Trademark Office.

A check for \$180.00 is also enclosed pursuant to 37 C.F.R. § 1.17(p) for filing this Information Disclosure Statement after three months as set forth in 37 C.F.R. § 1.97(c).

The Commissioner is hereby authorized to charge any additional fee or credit overpayment to our Deposit Account No. 08-1290. **An originally executed duplicate of this transmittal is enclosed for this purpose.**

Dated: January 12, 2006

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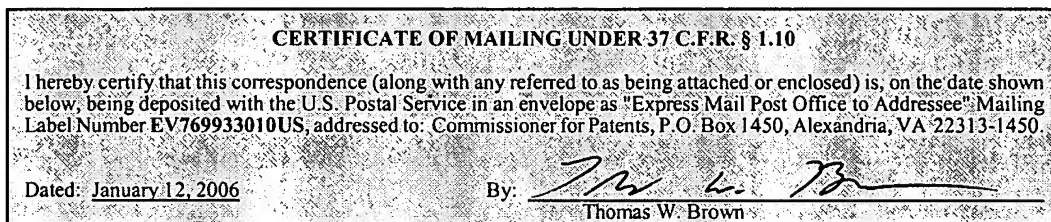
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INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
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Sir:

The citations listed below, copies attached, may be material to the examination of the above-identified application, and are therefore submitted in compliance with the duty of disclosure defined in 37 C.F.R. §§ 1.56 and 1.97. The Examiner is requested to make these citations of official record in this application.

In compliance with 37 C.F.R. § 1.98(a)(2) the applicant has not provided hard copies of cited U.S. Patents since the instant application was filed after June 30, 2003.

The following printed publications are referred to in the body of the specification:

- U.S. Patent No. 4,552,891 to Ho *et al.*;
- U.S. Patent No. 4,588,394 to Schulte *et al.*;
- U.S. Patent No. 4,902,505 to Pardridge *et al.*;
- U.S. Patent No. 5,004,697 to Pardridge;
- U.S. Patent No. 5,051,448 to Shashoua;
- U.S. Patent No. 5,130,129 to Pardridge ;
- U.S. Patent No. 5,147,855 to Gozes *et al.*;
- U.S. Patent No. 5,166,320 to Wu *et al.*;
- U.S. Patent No. 5,169,862 to Burke, Jr. *et al.*;
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- U.S. Patent No. 5,393,773 to Craig *et al.*;
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- U.S. Patent No. 5,670,477 to Poduslo *et al.*;
- U.S. Patent No. 5,801,161 to Merkus;
- U.S. Patent No. 5,864,037 to Chasin *et al.*;
- U.S. Patent No. 5,869,479 to Kreutner *et al.*;
- U.S. Patent No. 5,972,883 to Gozes *et al.*;
- U.S. Patent No. 6,042,579 to Elsberry *et al.*;
- U.S. Patent No. 6,117,454 to Kreuter *et al.*;
- U.S. Patent No. 6,132,764 to Li *et al.*;
- U.S. Patent No. 6,153,193 to Kabanov *et al.*;
- U.S. Patent No. 6,172,277 to Tate *et al.*;
- U.S. Patent No. 6,179,826 to Aebischer *et al.*;
- Auger *et al.*, "HLA-DR4 and HLA-DR10 Motifs That Carry Susceptibility To Rheumatoid Arthritis Bind 70-kD Heat Shock Proteins," *Nature Med* 2:306-310 (1996);
- Basu S. *et al.*, "CD91 is a common receptor for heat shock proteins gp96, hsp70, and calreticulin," *Immunity* 14: 303-313 (2001);
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- Bickel *et al.*, "Pharmacologic effects *in vivo* in brain by vector-mediated peptide drug delivery," *Proc. Natl. Acad. Sci. USA* 90:2618-2622 (1993);
- Borisova *et al.*, "Behavior of a Short preS1 Epitope on the Surface of Hepatitis B Core Particles," *Biol Chem* 380:315-324 (1999);
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- Curran M *et al.*, "HLA-DR antigens associated with major genetic risk for late-onset Alzheimer's disease," *NeuroReport* 8:1467-1469 (1997);
- Dubensky *et al.*, "Direct transfection of viral and plasmid DNA into the liver or spleen of mice," *Proc. Nat. Acad. Sci. USA*, 81:7529-33 (1984);
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- Fisher *et al.*, "(±)-cis-2-Methyl-spiro (1,3-oxathiolane-5,3') quinuclidine (AF102B): a new M₁ agonist attenuates cognitive dysfunctions in AF64A-treated rats," *Neurosci Lett* 102:325-331 (1989);
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- Galea E and Feinstein DL, "Regulation of the expression of the inflammatory nitric oxide synthase (NOS2) by cyclic AMP," *FASEB J* 13:2125-2137 (1999);
- Greengersen PK *et al.*, "The Share Epitope Hypothesis: An Approach to Understanding The Molecular Genetics of Susceptibility to Rheumatoid Arthritis," *Arthritis Rheum* 30:1205-1213 (1987);
- Ku *et al.*, "Potent Non-peptide Fibrinogen Receptor Antagonists Which Present An Alternative Pharmacophore," *J. Med. Chem.* 38:9 (1995);
- Levitzki A., "Targeting signal transduction for disease therapy," *Curr Opin Cell Biol* 8:239-244 (1996);
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- Lipman and Pearson, "Rapid and Sensitive Protein Similarity Searches," *Science* 227:1435-1441 (1985);
- McCurdy D *et al.*, "Delayed Repair of DNA Damage by Ionizing Radiation in Cells from Patients with Juvenile Systemic Lupus Erythematosus and Rheumatoid Arthritis," *Radiat Res* 147:48-54 (1997);

- Nepom GT *et al.*, "HLA Genes Associated With Rheumatoid Arthritis: Identification of Susceptibility Alleles Using Specific Oligonucleotide Probes," *Arthritis Rheum* 32:15-21 (1989);
- Pearson and Lipman, "Improved tools for biological Sequence comparison," *Proc. Natl. Acad. Sci. (USA)* 85:2444-2448 (1988);
- Pericak-Vance MA *et al.*, "Linkage Studies in Familial Alzheimer Disease: Evidence for Chromosome 19 Linkage," *Am J Hum Genet* 48:1034-1050 (1991);
- Pumpens P and Grens E., "Hepatitis B core particles as a universal display model: a structure-function basis for development," *FEBS Lett* 442:1-6 (1999);
- Stirttmatter WJ and Roses AD, "Apolipoprotein E and Alzheimer disease," *Proc Natl Acad Sci USA* 92:4725-4727 (1995);
- Wagner, *et al.*, "Transferin-polycation-DNA complexes: The effect of polycations on the structure of the complex and DNA delivery to cells," *Proc. Natl. Acad. Sci.*, 88:4255-4259 (1991);
- Weisgraber KH., "Apolipoprotein E distribution among human plasma lipoproteins: role of the cysteine-arginine interchange at residue 112," *J Lipid Res* 31:1503-1511 (1990);
- Weyand CM *et al.*, "The Influence of HLA-DRB1 Genes on Disease Severity in Rheumatoid Arthritis," *Ann Intern Med* 117:10 801-806 (1992); and
- Wolff *et al.*, "Direct Gene Transfer Into Mouse Muscle in Vivo," *Science*, 247:1456-68 (1990).

The following documents have been cited by the examiner in the parent application, Application No. 10/161,959, filed on 6/30/02:

- U.S. Patent No. 6,153,200 to Carson *et al.*;
- WIPO No. 97/34002 to Carson *et al.*
- WIPO No. 90/14835 to Carson *et al.*
- Walker *et al.*, "Proteopathy: The next therapeutic frontier?," *Curr Opin Investig Drugs*, 3(5):782-787 (2002);
- Fitzjohn *et al.*, "Age-related impairment of synaptic transmission but normal long-term potentiation in transgenic mice that overexpress the human APP695SWE mutant form of amyloid precursor protein," *J. Neuroscience*, 21(13):4691-4698 (2001);
- Chapman *et al.*, "Impaired synaptic plasticity and learning in aged amyloid precursor protein transgenic mice," *Nature Neuroscience*, 2:271-276 (1999);

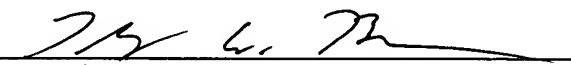
- Schenk *et al.*, "Potential treatment opportunities for alzheimer's disease through inhibition of secretases and A β immunization," *J. Mole. Neuroscience*, 17:259-267 (2001);
- Perdriger *et al.*, "Role of HLA-DR-DR and DR-DQ associations in the expression of extraarticular manifestations and rheumatoid factor in rheumatoid arthritis," *J. Rheumatology*, 24(7):1272-1276 (1997);
- Auger *et al.*, "A function for the QKRAA amino acid motif: mediating binding of DnaJ to DnaK," *J. Clin Invest*, 99(8):1818-1822 (1997);
- Singal *et al.*, "Genetics of rheumatoid arthritis (RA): two separate regions in the major histocompatibility complex contribute to susceptibility to RA," *Immunology Letters*, 69:301-306 (1999).

The following documents were provided to the examiner with an office action response from the parent application, Application No. 10/161,959, filed on 6/30/02:

- Vitolo *et al.*, "Amyloid β -peptide inhibition of the PKA/CREB pathway and long-term potentiation: reversibility by drugs that enhance cAMP signaling," *PNAS*, 99(20):13217-13221 (2002);
- Sun *et al.*, "Bilateral injection of isoproterenol into hippocampus induces alzheimer-like hyperphosphorylation of tau and spatial memory deficit in rat," *FEBS Letters*, 579:251-258 (2005);
- Gong *et al.*, "Persistent improvement in synaptic and cognitive functions in an alzheimer mouse model after rolipram treatment," *J. Clin. Invest.*, 114(11):1624-1634 (2004).

This Information Disclosure Statement under 37 C.F.R. §§ 1.56 and 1.97 is not to be construed as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any one or more of these citations constitutes prior art.

Dated: January 12, 2006



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FORM PTO-1449
(Modified)U.S. Department of Commerce
Patent and Trademark Office

Attorney Docket No.: UM-08550

Serial No.: 10/786,774

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Use Several Sheets If Necessary)Applicant: Joseph Holoshitz *et al.*

(37 CFR § 1.98(b))

Filing Date: 02/25/04

Group Art Unit: 1649

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	Serial / Patent Number	Issue Date	Applicant / Patentee	Class	Subclass	Filing Date
	1	4,552,891	11/12/85	Ho <i>et al.</i>	514	443	9/13/83
	2	4,588,394	05/13/86	Schulte <i>et al.</i>	604	9	03/16/84
	3	4,902,505	2/20/90	Pardridge <i>et al.</i>	424	85.7	4/25/88
	4	5,004,697	4/02/91	Pardridge	436	547	8/17/87
	5	5,051,448	9/24/91	Shashoua	514	547	5/07/90
	6	5,130,129	7/14/92	Pardridge	424	85.8	3/06/90
	7	5,147,855	9/15/92	Gozes <i>et al.</i>	514	12	7/07/89
	8	5,166,320	11/24/92	Wu <i>et al.</i>	530	395	04/02/90
	9	5,169,862	12/08/92	Burke <i>et al.</i>	514	450	11/18/91
	10	5,192,746	3/09/93	Lobl <i>et al.</i>	514	11	7/09/90
	11	5,354,844	10/11/94	Beug <i>et al.</i>	530	345	03/09/90
	12	5,393,773	2/28/95	Craig <i>et al.</i>	514	415	1/19/92
	13	5,525,727	6/11/96	Bodor	546	39	10/28/92
	14	5,539,085	7/23/96	Bischoff <i>et al.</i>	530	350	8/20/93
	15	5,554,639	9/10/96	Craig <i>et al.</i>	514	415	6/02/95
	16	5,559,103	9/24/96	Gaeta <i>et al.</i>	514	54	7/20/94
	17	5,576,423	11/19/96	Aversa <i>et al.</i>	530	388.75	12/02/94
	18	5,601,835	2/11/97	Sabel <i>et al.</i>	424	424	1/12/94
	19	5,618,803	4/08/97	Bodor	514	81	11/15/94
	20	5,643,207	07/01/97	Rise	604	93	06/27/96
	21	5,624,894	4/29/97	Bodor	514	2	4/27/95
	22	5,670,477	9/23/97	Poduslo <i>et al.</i>	514	2	4/27/95
	23	5,801,161	9/01/98	Merkus	514	52	6/17/96
	24	5,864,037	1/26/99	Chasin <i>et al.</i>	544	118	6/06/96
	25	5,869,479	2/09/99	Kreutner <i>et al.</i>	514	212	8/14/97
	26	5,972,883	10/26/99	Gozes <i>et al.</i>	514	12	3/30/95
	27	6,042,579	03/28/00	Elsberry <i>et al.</i>	604	891.1	04/30/97
	28	6,117,454	9/12/00	Kreutner <i>et al.</i>	424	490	5/27/97
	29	6,132,764	10/17/00	Li <i>et al.</i>	424	450	4/08/96
	30	6,153,193	11/28/00	Kabanov <i>et al.</i>	424	184.1	6/07/95
	31	6,172,277	01/09/01	Tate <i>et al.</i>	800	12	10/28/97
	32	6,179,826	1/30/01	Aebischer <i>et al.</i>	604	522	10/29/96
	33	6,153,200	11/2000	Carson <i>et al.</i>	424	201.1	

Examiner:

Date Considered:

EXAMINER:

Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 (Modified)		U.S. Department of Commerce Patent and Trademark Office		Attorney Docket No.: UM-08550	Serial No.: 10/786,774			
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use Several Sheets If Necessary) (37 CFR § 1.98(b))				Applicant: Joseph Holoshitz <i>et al.</i>				
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FOREIGN PATENTS OR PUBLISHED FOREIGN PATENT APPLICATIONS								
		Document Number	Publication Date	Country / Patent Office	Class	Subclass	Translation	
							Yes	No
	34	WO 97/34002	18.09.97	WIPO	A61K	37/02		
	35	WO 90/14835	13.12.90	WIPO	C12N	15/31		
OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication)								
	36	Auger I <i>et al.</i> , "HLA-DR4 and HLA-DR10 Motifs That Carry Susceptibility To Rheumatoid Arthritis Bind 70-kD Heat Shock Proteins," <i>Nature Med</i> 2:306-310 (1996)						
	37	Basu S. <i>et al.</i> , "CD91 is a common receptor for heat shock proteins gp96, hsp70, and calreticulin," <i>Immunity</i> 14: 303-313 (2001)						
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	41	Colaco CB <i>et al.</i> , "Deficient repair of O ⁶ -methylguanine in lymphocytes from rheumatoid arthritis families may be an acquired defect," <i>Clin Exp Immunol</i> 72:15-19 (1988)						
	42	Corder EH <i>et al.</i> , "Gene Dose of Apolipoprotein E Type 4 Allele and the Risk of Alzheimer's Disease in Late Onset Families," <i>Science</i> 261:921-923 (1993)						
	43	Corder EH <i>et al.</i> , "Protective effect of apolipoprotein E type 2 allele for late onset Alzheimer disease," <i>Nat Genet</i> 7:180-184 (1994)						
	44	Curran M <i>et al.</i> , "HLA-DR antigens associated with major genetic risk for late-onset Alzheimer's disease," <i>NeuroReport</i> 8:1467-1469 (1997)						
	45	Dubensky <i>et al.</i> , "Direct transfection of viral and plasmid DNA into the liver or spleen of mice," <i>Proc. Nat. Acad. Sci. USA</i> , 81:7529-33 (1984)						
	46	Eldred <i>et al.</i> , "Orally Active Non-Peptide Fibrinogen Receptor (GpIIb/IIIa) Antagonists: Identification of 4-[4-(Aminoiminomethyl)phenyl]-1-piperazinyl]-1-piperidineacetic Acid as a Long-Acting, Broad-Spectrum Antithrombotic Agent," <i>J. Med. Chem.</i> 37:3882 (1994)						
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	51	Ku <i>et al.</i> , "Potent Non-peptide Fibrinogen Receptor Antagonists Which Present An Alternative Pharmacophore," <i>J. Med. Chem.</i> 38:9 (1995)						
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(37 CFR § 1.98(b))					
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	60	Stirttmatter WJ and Roses AD, "Apolipoprotein E and Alzheimer disease," <i>Proc Natl Acad Sci USA</i> 92:4725-4727 (1995)			
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	62	Weisgraber KH., "Apolipoprotein E distribution among human plasma lipoproteins: role of the cysteine-arginine interchange at residue 112," <i>J Lipid Res</i> 31:1503-1511 (1990)			
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	64	Wolff <i>et al.</i> , "Direct Gene Transfer Into Mouse Muscle in Vivo," <i>Science</i> , 247:1456-68 (1990)			
	65	Walker <i>et al.</i> , "Proteopathy: The next therapeutic frontier?," <i>Curr Opin Investig Drugs</i> , 3(5):782-787 (2002)			
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	67	Chapman <i>et al.</i> , "Impaired synaptic plasticity and learning in aged amyloid precursor protein transgenic mice," <i>Nature Neuroscience</i> , 2:271-276 (1999)			
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	69	Perdriger <i>et al.</i> , "Role of HLA-DR-DR and DR-DQ associations in the expression of extraarticular manifestations and rheumatoid factor in rheumatoid arthritis," <i>J. Rheumatology</i> , 24(7):1272-1276 (1997)			
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	71	Singal <i>et al.</i> , "Genetics of rheumatoid arthritis (RA): two separate regions in the major histocompatibility complex contribute to susceptibility to RA," <i>Immunology Letters</i> , 69:301-306 (1999)			
	72	Vitolo <i>et al.</i> , "Amyloid β -peptide inhibition of the PKA/CREB pathway and long-term potentiation: reversibility by drugs that enhance cAMP signaling," <i>PNAS</i> , 99(20):13217-13221 (2002)			
	73	Sun <i>et al.</i> , "Bilateral injection of isoproterenol into hippocampus induces alzheimer-like hyperphosphorylation of tau and spatial memory deficit in rat," <i>FEBS Letters</i> , 579:251-258 (2005)			
	74	Gong <i>et al.</i> , "Persistent improvement in synaptic and cognitive functions in an alzheimer mouse model after rolipram treatment," <i>J. Clin. Invest.</i> , 114(11):1624-1634 (2004)			
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Examiner:			Date Considered:		
EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.					